

Food and Drug Administration, HHS

§ 73.200

fish feed use made with haematococcus algae meal may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Haematococcus algae meal shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.

Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.

Mercury, not more than 1 part per million.

Heavy metals (as Pb), not more than 10 parts per million.

Astaxanthin, not less than 1.5 percent.

(c) *Uses and restrictions.* Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing haematococcus algae meal shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 41584, July 6, 2000]

§ 73.200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Synthetic iron oxide for human food use shall conform to the following specifications:

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Mercury (as Hg), not more than 1 part per million.

(2) Synthetic iron oxide for dog and cat food use shall conform to the following specifications:

Arsenic (as As), not more than 5 parts per million.

Lead (as Pb), not more than 20 parts per million.

Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* (1) Synthetic iron oxide may be safely used for the coloring of sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(2) Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not

§ 73.250

21 CFR Ch. I (4–1–05 Edition)

necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 59 FR 10578, Mar. 7, 1994]

§ 73.250 Fruit juice.

(a) *Identity.* (1) The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.260 Vegetable juice.

(a) *Identity.* (1) The color additive vegetable juice is prepared either by expressing the juice from mature vari-

eties of fresh, edible vegetables, or by the water infusion of the dried vegetable. The color additive may be concentrated or dried. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.275 Dried algae meal.

(a) *Identity.* The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) *Uses and restrictions.* The color additive dried algae meal may be safely used in chicken feed in accordance